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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,410	05/07/2001	Gregory R. Reyes	4600-0183.26	2902
22918	7590	02/08/2005	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/851,410

Applicant(s)

REYES ET AL.

Examiner

Mary E. Mosher, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 December 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See attachment.
4. ☒ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 42-61.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Those rejections not repeated below have been withdrawn in view of applicant's amendments or arguments.

### ***Claim Rejections - 35 USC § 112***

Claims 45-47, 49-51, 58-61 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 remains indefinite in reciting "homologous" for reasons of record. Applicant argues that the term is sufficiently clear, but since neither the specification, the claims, nor the prior art indicate the extent of changes that are encompassed by this term, the rejection is maintained. This affects dependent claims 46-47.

Claim 49 remains confusing in reciting "at most about 25-30% base pair mismatches." "At most" indicates an upper limit, but "25-30%" indicates a closed range; which is intended?. Also, "at most about" is confusing. For example, 31% mismatches is "about 30%" but exceeds "at most 30%," would 31% mismatches be included or excluded from the claim? This affects dependent claims 50-51.

Applicants argue that the term "about" has been accepted under pertinent precedent. However, the rejection is not made on the grounds that "about" is indefinite, but because the combination of "about" with "at most" leads to confusion as to the scope of what is claimed, and because the claims mix open and closed terms and thereby confuse the scope of the claims. Claims reciting "about 25%" or "about 30%" or

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"at most 30%" would be clear, but the confusion comes with combination of different types of limitations in the same claim.

Claim 58-61 remain confusing in using both open "comprising" and closed "about 100 to about 300 amino acids" (or base pairs). Do the claims include or exclude peptides with, say, 400 amino acids of HEV ORF2? Would this invention be better defined by, say, a claim to a composition comprising a fusion peptide with 30-100 amino acids of SEQ ID NO:8 linked to a heterologous sequence?

Claims 44-61 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated peptides which are specifically immunoreactive with antibodies present in individuals infected with hepatitis E virus (HEV), and for immunogenic compositions comprising the same, the specification does not reasonably provide enablement for all the peptide fragments and variants encompassed by the claims or for the full scope of protective vaccines. Applicant's response does not address the issue of the failure to present an enabling use for peptides which are not specifically immunoreactive with antibodies present in HEV-infected individuals. Applicant argues that preventing infection is not the sole benefit. The examiner agrees with this position, which is precisely why the claims are indicated as enabling for immunogenic compositions. However, the examiner maintains that the ordinary meaning of the term "vaccine" is a composition which induces an immune response which prevents infection. Since the specification does not contain any other explicit definition of the term "vaccine" the ordinary meaning of the term is applied, and according to this ordinary meaning the specification does not teach an effective vaccine

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(absent undue experimentation). Therefore, it is maintained that the claims are enabled for a useful immunogenic composition, but not for a vaccine.

***Double Patenting***

Claims 42, 45, 48, 49, 52-55, 58-59 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-10, 24-29 of U.S. Patent No. 5824649. Applicant did not argue this rejection.

Claims 54, 55, 58, 59 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6214970 or 6291641 or 5770689, or claims 1, 3, 4 of U.S. Patent No. 5885768. Applicant did not argue this rejection.

Claims 43, 44, 46, 47, 50, 51, 56, 57, 60, 61 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5741490. Applicant did not argue this rejection.

Claims 56, 57, 60, 61 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/165868.

Claims 43, 44, 46, 47, 50, 51, 56, 57, 60, 61 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 23 of copending Application No. 09/769066.

Applicant's offer to submit terminal disclaimers once allowable subject matter is indicated is noted.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1/11/05

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800** 1660